

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SHIRE LLC, et al.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS LLC et al.,

Defendants.

C.A. No. 2:11-cv-03781-SRC-CLW
(CONSOLIDATED)

SHIRE LLC, et al.,

Plaintiffs,

v.

WATSON LABORATORIES, INC. et al.,

Defendants.

C.A. No. 2:12-cv-00083-SRC-CLW

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**REPLY MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION FOR
PARTIAL SUMMARY JUDGMENT OF NO WILLFUL INFRINGEMENT**

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I. INTRODUCTION

In its opposition to Defendants’ motion for partial summary judgment of no willful infringement, Shire now advocates willfulness claims not previously pled or disclosed, and presents a storyline intended to create the appearance of factual disputes. Indeed, Shire continues to use misdirection and sleight of hand to overly complicate and conflate issues, in the hopes of drawing the Court’s attention away from the governing law and the narrow scope of the willfulness claims Shire has repeatedly and consistently disclosed—even after the filing of this motion. Shire’s futile attempt to preserve its willfulness claims by presenting new arguments in its opposition brief is impermissible.

While the “facts” presented by Shire are certainly disputed, those disputes do not preclude summary judgment because even Shire stops short of calling the identified activity “infringing”—and where there has not been infringement, there cannot be willful infringement. Instead, the activity Shire identifies is all of the sort that Congress envisioned, encouraged, and fully blessed in the form of the Hatch-Waxman Act’s “safe harbor” provisions. Because Shire cannot support a claim for willful infringement, Defendants’ motion should be granted.

II. ARGUMENT

A. Shire’s Argument That The ANDA Defendants Induce JM Fails

Shire devotes the bulk of its opposition brief to a revisionist history of “facts” regarding JM’s development of lisdexamfetamine dimesylate API and JM’s consideration of the patents-in-suit. The irrelevance of this evidence is discussed below in Section II.B and the inaccuracies in Shire’s portrayal are addressed in the accompanying Responses to Shire’s Supplemental Facts.¹

¹ Aspects of Shire’s recitation draw from inadvertently produced privileged documents that are the subject of JM’s pending Appeal (D.I. 552). To the extent the Court finds that Shire’s

(cont’d)

But even if accepted as true, Shire's narrative does not present any serious challenge to Defendants' assertion that the sole act of past infringement alleged against the ANDA Defendants—and the sole predicate basis for a finding of willfulness—is the filing of the ANDAs.² In fact, Shire never denies that the filing of an ANDA is a legally insufficient basis on which to find willful infringement, even when the ANDA is allegedly baseless.³ *See, e.g., Celgene Corp. v. Teva Pharm. USA, Inc.*, 412 F. Supp. 2d 439, 445 (D.N.J. 2006). Shire has thus failed to raise any genuine issue of material fact regarding the willfulness claim it pled in its Amended Complaints and identified in its infringement contentions to the ANDA Defendants.

Shire's new theory, based on an alleged cooperative venture between the ANDA Defendants and JM, is both improper and insufficient to defeat summary judgment. Under this circular theory, Shire suggests that willfulness claims are available against the ANDA Defendants because they "have induced and contributed to JM's willful infringement." (Shire's Opp. Br. (D.I. 571) at 16.) Shire merely presupposes that JM and the ANDA Defendants are in a cooperative venture, citing to *Forest Laboratories, Inc. v. Ivax Pharmaceuticals, Inc.*, 501 F.3d 1263 (Fed. Cir. 2007). (Shire's Opp. Br. at 3, 6, 7, 16-18.) In fact, *Forest* does not hold that any situation in which a third party supplies API to an ANDA filer amounts to a cooperative venture.

(cont'd from previous page)

assertions based on such documents raise fact disputes and defeat summary judgment, JM reserves the right to renew its request for summary judgment if the Appeal is granted.

² *See, e.g.,* Responses to Shire's Supplemental Facts at Facts 59, 66.

³ Shire's brief seems to suggest that it need not respond to Defendants' legal argument because JM's status as an API supplier rather than an ANDA filer somehow obviates the effect of the ANDA-related case law cited in Defendants' brief. (Shire's Opp. Br. at 6.) This effort rings hollow. The fact remains that the only two acts of infringement alleged by Shire (the generics' inclusion of paragraph IV certifications in their ANDAs, and JM's written authorization allowing each ANDA to reference its DMF 22442) relate exclusively to the ANDA filings. Thus, the ANDA-related case law is plainly applicable.

Rather, the court found that a cooperative venture existed based on the facts of record in that case. By contrast, Shire has not established the existence of a cooperative venture, or any relationship between the ANDA Defendants and JM that amounts to anything more than an ordinary business relationship resulting from arms-length transactions. In any event, the cooperative venture addressed in *Forest* bore on the question of induced infringement, not willfulness. *Forest*, 501 F.3d at 1272. Finally, even if a “cooperative venture” did exist and even if JM were held to be a willful infringer, that finding does not automatically extend to any indirect infringers. *See, e.g., Primos, Inc. v. Hunter’s Specialties, Inc.*, No. C01-0004, 2004 U.S. Dist. LEXIS 31226, at *55-60 (N.D. Iowa Sept. 7, 2004) (“[D]amages owed by [defendants] for inducing direct infringement cannot be multiplied due to [the direct infringer’s] willfulness.”), *aff’d* 451 F.3d 841 (Fed. Cir. 2006).

However, the Court need not grapple with Shire’s effort to extend its flawed reading of *Forest* because Shire never identified inducement and contribution to JM’s willful infringement in its L. Pat. R. 3.1(h) disclosures to the ANDA Defendants. As addressed in Defendants’ opening brief (D.I. 519) at Sec. II.B and confirmed in Shire’s L.R. 56.1 Responses (D.I. 572 at Fact 13), Shire’s L. Pat. R. 3.1(h) willful infringement disclosures provide very limited allegations against the ANDA Defendants and do not mention JM: “Upon information and belief, [the ANDA Defendants] filed [their] ANDA[s] despite an objectively high likelihood that the Asserted Claims are valid and that [the ANDA Defendants’] product[s] infringe[] the patents-in-suit.” The contentions contain *no* further allegation of willful infringement by the ANDA Defendants, and make no mention of Shire’s new theory of willfulness by inducing or contributing to JM’s acts. This late-added theory flies in the face of the Local Rules and denies Defendants “adequate notice and information with which to litigate their case.” *Shire LLC v. Amneal Pharms., LLC*, No. 2:11-cv-03781, 2013 U.S. Dist. LEXIS 180920, at *5 (D.N.J. Dec.

23, 2013) (quoting *Computer Accelerations Corp. v. Microsoft Corp.*, 503 F. Supp. 2d 819, 822 (E.D. Tex. 2007)).

Notably, Shire's characterizations of the willfulness claims against the ANDA Defendants in the Pre-Trial Order—filed *after* this motion was filed—are even narrower and speak *only* to future claims of willful infringement in the event there is a commercial launch. (D.I. 546, at 17, 20, 23, 26, 29, 32-33.) The Court should reject Shire's desperate attempt to keep its willfulness claim in play by introducing legally defective and factually unsupported new claims in its opposition brief. *See, e.g., Safeclick, LLC v. Visa Intern. Service Ass'n*, 208 Fed. App'x 829, 835-36 (Fed. Cir. 2006) (affirming summary judgment of non-infringement where district court refused to consider patentee's new infringement theory raised in opposition brief); *O2 Micro Int'l Ltd. v. Monolithic Power Sys.*, 467 F.3d 1355, 1369 (Fed. Cir. 2006) (same); *King Pharms., Inc. v. Sandoz, Inc.*, No. 08-5974 (GEB), 2010 U.S. Dist. LEXIS 127647 (D.N.J. Sept. 7, 2010) (granting motion *in limine* to preclude theories not identified in contentions).

B. Shire's Allegations Against JM Are Equally Flawed

1. Shire Has Not Alleged Actual Past Infringement By JM, Let Alone Willful Past Infringement

JM's Opening Brief asserted that, with regard to JM, the single alleged act of *past* infringement is JM's written authorization allowing each ANDA to reference its DMF. Shire alleged this one act of past infringement in each of its five amended complaints:

Upon information and belief, the inclusion of Johnson Matthey's written authorization in the [] ANDA[s] for the purpose of supporting the [] ANDA[s] is an act of infringement of one or more claims of the [] patent[s-in-suit] under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly in a cooperative venture, including by inducement and/or contributory infringement.

(*See, e.g.,* D.I. 219, ¶¶ 59, 85, 98, 124.) Though Shire refuses to admit this fact outright, its carefully worded objections verify the accuracy of JM's statement.

In response to Defendants’ Fact Statement No. 10, Shire disputes that the written authorization “is the only act of infringement by Johnson Matthey that is alleged by Shire,” and insists that it has put forth other allegations under §§ 271(a), (b), and (c).⁴ (D.I. 572, at Fact 10.) However, Shire only points to its allegations of *future* infringement—confirming that JM’s written authorization is the single accused act of *past* infringement. Specifically, Shire is forced to cite to identical paragraphs in its five amended complaints against the Defendants:

Upon information and belief, Johnson Matthey’s commercial manufacture, use, sale, offer for sale and/or importation into the United States of the lisdexamfetamine dimesylate API that **will be used** as the main component in the [ANDA Defendant’s] Proposed Product that is the subject of [its] ANDA [] **will infringe** one or more claims of the [] patent directly under 35 U.S.C. § 271(a) and/or indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

(See D.I. 572, at Fact 10 (citing to D.I. 219 ¶¶ 87, 100, 126; D.I. 220 ¶¶ 84, 97, 125; D.I. 129 ¶¶ 85, 100, 164; D.I. 221 ¶¶ 84, 97, 123; D.I. 222 ¶¶ 85, 97, 123) (emphasis added).)⁵

Shire also cites to its Disclosure of Infringement Contention to Johnson Matthey (*i.e.* Sawchuck Decl. Ex. 173 D.I. 594-13), and in particular to pages 4-6, which purport to satisfy the requirements of Local Patent Rule 3.1(a). (D.I. 572, at Fact 10.) Again, other than the ANDA-related activity, the Infringement Contentions identify only *future* infringement by JM that *might* occur only if the ANDA Defendants market their proposed ANDA products. (Response to Shire Fact 77.) It is not disputed that Defendants have not to date marketed their ANDA products.

Shire’s L. Pat. R. 3.1(h) disclosure of the basis for its willfulness allegations against JM is similarly limited to potential future conduct: “JM makes, uses, sells, offers for sale, and/or

⁴ Shire also includes § 271(e)(2) in this list, though the relevant allegations cited are those already quoted above on written authorization. (See D.I. 219, ¶ 59, 85, 98, 124.)

⁵ Shire also cites back to the many identical “written authorization” paragraphs. (See D.I. 572 at Fact 10, citing to D.I. 219 ¶¶ 85, 98, 124; D.I. 220 ¶¶ 82, 95, 123; D.I. 129 ¶¶ 85, 98, 124; D.I. 221 ¶¶ 82, 95, 121; D.I. 222 ¶¶ 82, 95, 121).

imports the *lisdexamfetamine dimesylate* API in the Defendants' products despite an objectively high likelihood that the Asserted Claims are valid and that Defendants' products infringe the patents-in-suit." (D.I. 594-13 at 340 (emphasis added).) Though drafted in the present tense, the allegation is inherently prospective because the "Defendants' products" remain hypothetical.

Perhaps most telling, in the Pre-Trial Order submitted *after* this motion was filed, Shire described its willfulness claims against JM strictly in terms of potential future acts:

Shire seeks a further judgment declaring that infringement of the patents-in-suit is willful **if** Johnson Matthey commercially manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of any of the Defendants' ANDAs and/or DMF No. 22442 that infringes the patents-in-suit.

(D.I. 546 at 32 (emphasis added).) This request is virtually identical to the Prayer for Relief included each of Shire's Amended Complaints:

A judgment declaring that infringement of the '735 patent is willful **if** Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202802 and/or DMF No. 22442 that infringes the '735 patent.

(*See, e.g.*, D.I. 219, at p. 52, Sec. xiv.) In sum, Shire plead this case in the first instance as a traditional ANDA case. To defeat JM's motion to dismiss, Shire argued vigorously that JM should be treated as if it were an ANDA filer. Shire served contentions narrowly describing both the infringement and willfulness claims against JM, and never amended those contentions to expand its claims. And most recently, in a Pre-Trial Order that Shire had reason to believe would strictly constrain its proofs at trial, Shire described its willfulness claim against JM as strictly prospective. As a result, Shire should not now be permitted to belatedly expand the willfulness claim to address illusory acts of past direct infringement.

2. The Evidence Shire Cites Is Protected Safe Harbor Activity

Even if Shire could expand its pleadings to encompass past acts, the purported "evidence in the record supporting Shire's assertion that Johnson Matthey has manufactured, used, offered

to sell, and sold lisdexamfetamine API” also does not raise a genuine fact dispute because even Shire does not go so far as to assert that such acts constitute “patent infringement.” (*See* D.I. 572 at Fact 17.) Nor could Shire credibly contend that such acts constitute infringement in view of the safe harbor provision of § 271(e)(1), which provides that:

It **shall not** be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(emphasis added). JM’s activities described in Shire’s Responses to Facts 17 and 19, (D.I. 572), fall squarely within the safe harbor and thus cannot be infringing acts under the statute. *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 206 (2005) (Congress “exempted from infringement *all* uses of patented compounds ‘reasonably related’ to the process of developing information for submission under *any* federal law regulating the manufacture, use or distribution of drugs.” (citation omitted) (emphasis in original)). By not claiming the past activity as infringing and not seeking related damages relief,⁶ Shire effectively concedes that such activity is protected by the safe harbor. Indeed, that conclusion is compelled by the evidence, which demonstrates that each action listed was taken with regard to parties either filing or contemplating NDA or ANDA submissions. (*See* Response to Fact 66.)

3. Shire’s Focus on JM’s Patent Analyses Is A Mere Distraction

Shire devotes much of its brief to an examination of JM’s employees’ communications about and analyses of the Shire patents. (Opp. Br. at 7-14.) Even viewed in the light most

⁶ (*See, e.g.*, D.I. 219, at pp. 50-73 (including no present claim for damages); Proposed Pretrial Order (D.I. 546) at 17, 20, 23, 26, 29, 32, 46, 76 (indicating that a) Shire will not call witnesses for damages; b) Shire will not offer evidence for damages; and c) Shire does not seek damages for past infringement from any Defendant).)

favorable to Shire for purposes of summary judgment, Shire's allegations do not raise a material fact issue since Shire has not properly presented claims of actual past infringement, and has not advanced a willfulness claim on the basis of such past acts. The reason why Shire is struggling to keep its willfulness claim in play is plain. Shire is desperate to preserve some legal basis to put before the Court at every possible opportunity JM's privileged internal analyses reflected in documents that Shire should not be permitted to even have or use for any purpose. Although Magistrate Judge Waldor held that JM waived its attorney-client privilege and work-product protection, JM has appealed that decision (D.I. 552), and Shire should not be permitted to use these documents while its appeal is pending. *See* Fed. R. Civ. P. 26(b)(5)(B) (requiring party to not use documents subject to a claim of privilege). Moreover, Shire's brief and facts also improperly use documents to which Roxane has asserted a claim of attorney-client privilege, which is also improper under Rule 26(b)(5)(B).

Shire's references to these documents in multiple submissions in relation to virtually every issue in the case leaves little doubt that Shire's goal is to prejudice the mind of the fact finder against the Defendants and cast doubt on the viability of their arguments. Defendants respectfully submit that the Court should not facilitate Shire's efforts and should instead grant summary judgment of no willfulness based on the lack of a material factual dispute.

C. Shire Cannot Meet The Objective Prong Of Willfulness

Even if the facts adduced by Shire in its opposition were both accepted as true and considered relevant to the "subjective prong" of the willfulness inquiry,⁷ Shire fails to point to

⁷ Evidence regarding the subjective prong of *Seagate* is irrelevant to the willfulness inquiry if plaintiff cannot first satisfy the objective prong. *See DePuy Spine*, 567 F.3d at 1337 (declining to address subjective prong where plaintiff did not meet objective prong); *Tarkus Imaging, Inc. v. Adobe Sys., Inc.*, 867 F. Supp. 2d 534, 538 n.4 (D. Del. 2010) ("[T]he Court may only proceed to the subjective second-prong inquiry if the objective prong is first satisfied.").

any evidence in support of the “objective prong” of willfulness as required by the *In re Seagate* willful infringement standard. 497 F.3d 1360 (Fed. Cir. 2007) (en banc).

The objective prong of the *Seagate* analysis evaluates the reasonableness of the accused infringers’ defenses. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003, 1006 (Fed. Cir. 2012), *cert. denied*, 133 S. Ct. 932 (2013). Under *Seagate*, the patentee must prove “by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent.” *Id.* It is well established that “both legitimate defenses to infringement claims and credible invalidity arguments demonstrate the lack of an objectively high likelihood that a party took actions constituting infringement of a valid patent.” *Black & Decker, Inc. v. Robert Bosch Tool Corp.*, 260 F. App’x 284, 291 (Fed. Cir. 2008). A defense need not be ultimately successful to rebut the first prong. *See DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1335-37 (Fed. Cir. 2009). Moreover, of particular relevance here, “[t]he state of mind of the accused infringer is not relevant to this objective inquiry.” *Seagate*, 497 F.3d at 1371; *Masimo Corp. v. Philips Elecs. N. Am. Corp.*, No. 09-80-LPS-MPT, 2013 U.S. Dist. LEXIS 83704, at *5-21 (D. Del. June 14, 2013) (refusing to consider evidence relevant to subjective prong including the “parties’ state of mind” where patentee could not meet objective prong).

In this case, Defendants have put forth, *inter alia*, defenses of patent invalidity and of non-infringement under the §271(e)(1) safe harbor. In its opposition Shire does not even address these defenses, let alone put forward evidence that such defenses are objectively unreasonable. Indeed, Defendants have moved for summary judgment on certain of these invalidity defenses (D.I. 499)—resulting in Shire’s immediate voluntary withdrawal of the claims addressed. (D.I. 544.) Credible defenses of invalidity militate against a finding of willfulness. *See, e.g., Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F.3d 1305, 1319-20 (Fed. Cir. 2010)

(upholding jury’s verdict of nonobviousness while reversing denial of JMOL of no willfulness because defendant “was not objectively reckless” in relying on obviousness defense); *TGIP, Inc. v. AT&T Corp.*, 527 F.Supp. 2d 561, 579 (E.D. Tex. 2007) (granting JMOL of no willfulness “[e]ven though [defendant] ultimately did not prove its invalidity defense by clear and convincing evidence” because “its position was hardly objectively unreasonable”). The evidence in support of Defendants’ invalidity arguments—and Shire’s reaction to Defendants’ summary judgment motion—is at least sufficient to establish that these defense are not “objectively unreasonable” as a matter of law. Because Shire cannot meet the objective prong of the *Seagate* analysis, the willfulness inquiry should end there.

D. The Alleged Future Infringement By Defendants Is Still Speculative

As explained in Section III.C. of Defendants’ Opening Brief and in this Court’s holding in *Celgene Corp. v. Teva Pharmaceuticals USA, Inc.*, 412 F. Supp. 2d 439, 445 (D.N.J. 2006), willfulness claims are not permissible for future conduct, like the contemplated future commercial activity alleged here. Though Shire repeatedly uses the word “commercial” in its opposition brief to imply that actionable commercial activity has taken place, Shire nevertheless concedes that this activity has not yet occurred:

Moreover, the potential commercial sales by the ANDA Defendants is **right around the corner**. The “30-month stay” is nearly complete, and the ANDA Defendants **could commercially launch** their products unless the Court precludes them prior to that time, i.e., by granting Shire’s case-dispositive motion for summary judgment (ECF No. 496), a preliminary injunction, or some other decision on the merits. Thus, Defendants’ request that Shire’s willful infringement claims be dismissed with prejudice **because “there has been no commercial launch of the generic products at issue”** is specious. (Defs. Br. at 6 n.3; Defs. Motion.)

(Shire’s Opp. Br. at 6-7 (emphasis added).)

Shire’s urging that its willfulness claims on the future conduct are sustainable because “the potential commercial sales by the ANDA Defendant is [*sic*] right around the corner” is

insufficient. (Shire's Opp. Br. at 6; *see also id.* at 18, 19.) This argument was tried and rejected in *Medicines Co. v. Mylan, Inc.*, No. 11-cv-1285, 2013 U.S. Dist. LEXIS 176269 (N.D. Ill. Dec. 16, 2013). In that ANDA case, Shire's own counsel sought to avoid summary judgment of no willfulness against its brand name client by arguing "that [the ANDA filer Defendant] will willfully infringe the patents-in-suit 'if [Defendant] commercially manufactures, uses, sells, offers to sell, or imports its generic [] product in the future.'" *Id.* at *76. The Court rejected this argument, admonishing Shire's counsel as follows:

TMC, however, does not cite any authority suggesting that this type of declaratory relief is appropriate. Nor does TMC cite any facts to warrant this type of declaratory relief. "Perfunctory and undeveloped arguments, and arguments that are unsupported by pertinent authority, are waived." *United States v. Hook*, 471 F.3d 766, 775 (7th Cir. 2006). The Court, therefore, grants Mylan's motion for summary judgment with respect to TMC's willful infringement claim. *See Giffney Perret, Inc. v. Matthews*, No. 07 C 0869, 2009 U.S. Dist. LEXIS 23531, 2009 WL 792484, at *16 (N.D. Ill. Mar. 24, 2009) (granting partial summary judgment to the defendant because the plaintiffs "undeveloped arguments amounted] to a waiver of Plaintiff's opposition to Defendants' motion for summary judgment").

2013 U.S. Dist. LEXIS 176269, at *77-78. Likewise, this Court should reject Shire's attempt to preserve a speculative claim for future willful infringement in this case.

E. Shire's Exceptional Case Claims Are Of No Moment

Throughout its opposition brief, Shire references its 35 U.S.C. § 285 "exceptional case" claim as a basis for denying summary judgment. Specifically, Shire presents the backwards and misleading argument that, because a finding of willfulness may be relevant to a subsequent exceptional case analysis, willfulness claims should automatically survive summary judgment where the plaintiff intends to seek an exceptional case ruling. While willful infringement can be a predicate for an exceptional case, it is illogical to accept that the existence of an exceptional case claim compels denial of summary judgment on the predicate claim. *See Celgene*, 412 F. Supp. 2d at 445 ("This holding [striking willfulness claims] does not prohibit plaintiffs from

applying for attorney's fees under the 'exceptional cases' provision of Section 285 if they prevail.").

III. CONCLUSION

For the reasons set forth above and in Defendants' opening brief, the Court should grant summary judgment of no willful infringement.

Dated: March 31, 2014

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